APR 2 6 2012

K120437 - 510(k) Summary
Twister™ Side-Firing Fiber Optic Delivery System

Submitter's Name
Biolitec SIA

Address
Kaniera iela 10a, Riga, LV-1063
Latvia

Telephone Number, Contact Person and Date Prepared
Phone: (413) 525-0600/ 413 250-0779 (Cell)
Facsimile: (413) 525-0611

Contact Person: Harry Hayes, Ph.D. – Regulatory Consultant
Date prepared: February 10, 2012

Name of Device and Name/Address of Sponsor

Twister™ Side-Firing Fiber Optic Delivery System

Biolitec SIA
Kaniera iela 10a, Riga, LV-1063
Latvia

Classification Name
Surgical laser & accessories

Common Name of Device
Twister™, SF & L

Predicate Devices
Twister™ Side Fire Fiber Optic Delivery System, (K112987)
Evolve® 980-1470nm Multiwavelength Diode Laser, (K112013)

Intended Use/Indication for Use
The Twister™ Side-Fire Fiber Optic Delivery System is a delivery accessory used to deliver optical energy and is indicated for use in general surgical applications in combination with any SMA-compatible laser system also indicated for the same applications. It is indicated for use in hemostasis, ablation and vaporization of soft or fibrous tissue in any surgical discipline in contact or non-contact mode with a compatible laser marketed for the desired application. The system can be used with

or without a standard viewing scope. It can be inserted through the working channel of a cystoscope, urethroscope, or any other viewing scope.

Technological Characteristics
The Biolitec SIA Twister™ Side-Fire Fiber Optic Delivery System contains identical components and identical patient-contact materials as the cleared Biolitec Medical Devices, Inc. Twister™ Side Fire Fiber Optic Delivery System.

Twister is a fiber optic delivery system designed to deliver optical energy from a surgical laser to soft or fibrous tissue for the indicated uses. The distal end of the Twister possesses a slight bend at the capillary tip, producing 30° lateral firing which is identical to the predicate. The fiber makeup remains silica, silica cladding, hard plastic cladding, and Tefzel jacketing as is the predicate. The numerical aperture (NA) of the fiber however is 0.26/ 0.37 (whereas the predicate is 0.22/ 0.37) giving a better coupling efficiency and correcting for the truncation in power transmission seen with the predicate fiber when using larger NA lasers.

Performance Data
Since the performance of the Twister™ Side-Fire Fiber Optic Delivery System is well established and documented on soft tissue no performance testing is being specifically included in this submission.

Substantial Equivalence
The Twister™ Side-Fire Fiber Optic Delivery System is as safe and effective for these Indications for Use as the Biolitec Medical Devices, Inc's Side Fire Fiber Optic Delivery System. Thus, the Twister™ Side-Fire Fiber Optic Delivery System for Biolitec SIA is substantially equivalent to its predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Biolitec SIA
% Genmarhay BDA
Harry Hayes, Ph.D.
1349 Main Road
Granville, Massachusetts 01034

APR 2 6 2012

Re: K120437
Trade/Device Name: Twister™ Side-Firing Fiber Optic Delivery System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: April 11, 2012
Received: April 13, 2012

Dear Dr. Hayes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K120437

Device Name: Twister™ Side-Firing Fiber Optic Delivery System

Indications for Use: The Twister™ Side-Firing Fiber Optic Delivery System is intended for use as a fiber optic delivery system in conjunction with any surgical laser with SMA 905 compatible connector. The Twister™ Side-Firing Fiber Optic Delivery System is indicated for hemostasis, ablation and vaporization of soft or fibrous tissue in any surgical discipline in contact or non contact mode with a compatible laser marketed for the desired application. The system can be used with or without a standard viewing scope. It can be inserted through the working channel of a cystoscope, urethroscope, or any other viewing scope.

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___√___ OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120437